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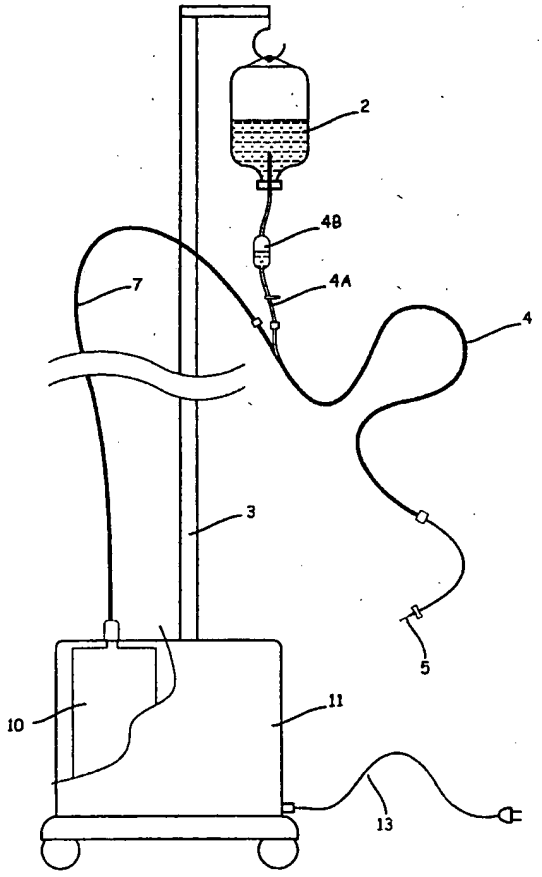
(54) **Title:** HEATING SYSTEM FOR WARMING A PHYSIOLOGIC FLUID TO BE INFUSED INTO A PATIENT



(57) **Abstract:** A system for in-line heating of medical fluids supplied to a patient, comprising a container (2) of physiologic fluid to be infused into a patient and a flexible supply conduit (4; 31; 34; 21) connected to said container (2) and terminating at one end with an infusion device (5), with an infrared light source (10) being connected at one end of a first optical cable (7; 37). Distributed converting means (8; 13; 23; 33) are provided at the other end of said optical cable (7; 37) for receiving the IR power from said source (10) and converting it into heat, and distributed heat exchanging means are further provided for progressively transferring said heat to the fluid to be infused that flows in said flexible tube to warm it.

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"HEATING SYSTEM FOR WARMING A PHYSIOLOGIC FLUID TO BE INFUSED INTO A PATIENT"

Field of the Invention

This invention is directed generally to fluid warming devices, and more particularly to a system for warming a physiologic or medical fluid, while the fluid is being infused into a patient.

Background of the Invention

In numerous medical procedures it is necessary to supply medical fluid to a patient, such as blood or blood products, as well as saline, anaesthetics and other medical fluids, both in operating rooms and emergency wards.

Properly warming such fluids is still a major problem, particularly when relatively large amount of fluids are to be warmed.

The warming devices fall into two main categories, namely the in-line warmers which heat fluid flowing in a path to the patient and batch warmers which heat fluid in a batch, the fluid then being placed in a separate delivery system for supplying the patient.

The present invention relates to an in-line warming device or system for warming a fluid which is being supplied to a patient.

During surgery and intensive treatments, medical liquids and/or blood are to be administered to a patient by intravenous injection. For many surgical procedures, blood must often be warmed to prevent patient's hypothermia and the amount of liquid to be warmed can be large, such as for example when a patient haemorrhages during surgery or in emergency wards.

The blood is usually stored at about 4°C, while the physiological and medical fluids are stored at room temperature. During the infusion, the patient's blood is mixed with the infusion liquids and is further cooled by these latter. Moreover the patient is often under anhestesia or inconscious so that the organism is unable to activate the usual defensive reactions to prevent a state of general hypothermia. This is not only uncomfortable to the patient, but can also severely interfere with other clinical aspects such as reaction to drugs, haemorrhage, cardiac rhythm, etc.

For accident victims or other emergency cases, the time required to warm blood for transfusion is often a critical factor, but on the other hand a quick warming or a locally excessive warming of the fluid can be very detrimental.

Many approaches have been suggested for meeting the need of an effective and reliable apparatus for quickly warming (even large amounts of) medical fluids to approximate body temperature.

US-A-4 759 749 discloses a portable unit for heating physiological fluids using a disposable heat exchanger in which a fluid heated by an electric heating member circulates.

US-A-4 532 414 discloses an in-line fluid warmer for heating parenteral fluids, particularly blood, supplied from a fluid container through a flexible supply conduit, including an enclosure containing a heated plate having a sinuously-shaped groove configured to accept and hold a length of the supply conduit in heat transfer relationship with the plate.

US-A-4 038 519 discloses a flexible tube incorporating resistance heating conductors for warming the blood flowing in the tube.

The use of microwaves for warming fluids to be supplied to a patient has been known for both batch warmers and in-line warmers. More precisely U.S Pat. No. 3,963,892 of Camph et al issued Jun. 15, 1976 shows in-line heating by microwaves of blood being passed from a container to a patient.

EP-A-307 895 suggest to use microwaves for local heating of blood or plasma contained in a bag, and US-A- 5 180 896 provides a source of electromagnetic radiation for warming the fluid passing in a heating zone of a housing.

US-A-5 180 896 discloses a system in which microwaves are used for warming the fluid and the temperature of such fluid is sensed by receiving infrared energy from the medical fluid as it flows within a sterile and disposable tube from a fluid source to a patient.

The known apparatuses have several drawbacks such as complicate arrangements, the need of an additional fluid as a heat exchanger, or the use of electrical devices in

closed relationship with the fluid to be infused, with this latter often being electrically conductive because of its salts content, that are to meet safety standard.

Moreover most of the known systems are not capable of maintaining the fluid temperature up to the patient circulatory system, allowing a temperature loss along the infusion line. This effect is more evident in infusion systems operating at a low flow rate.

Further some devices for in-line warming strongly stiffen the tube connecting the fluid container with the infusion device.

Object of the Invention

The blood warmer of the present invention seeks to overcome the disadvantages and limitations of the prior art fluid warming devices by providing an apparatus which effectively and quickly warms the physiologic fluid to the proper body temperature (normothermia) with great safety.

The object of the present invention is to overcome the disadvantages and limitations of prior art blood warming devices, by avoiding the use of electrical (and potentially dangerous) conductors to heat the fluid, eliminating the need of additional fluids, without mechanical moving parts such as pumps, and without substantially altering the flexibility of the administering tube while warming the liquid flowing in the tube in an easy and controllable manner.

Disclosure of the Invention

According to the invention, these objects are achieved through a system for in-line heating of medical fluids supplied to a patient as claimed in claim 1.

Further advantageous characteristics of the invention are recited in the dependent claims.

Brief Description of the Drawings

The invention will now be disclosed with reference to the attached drawings illustrating preferred but non-limiting embodiments thereof, in which:

Fig. 1 generally illustrates a first embodiment of the system according to the invention;

Fig. 2a shows an enlarged detail in cross section of the coupler of Fig. 1;

Fig. 2b shows an enlarged detail in cross section along line II-II of the flexible tube of Fig. 2;

Fig. 3 generally illustrates a second embodiment of the system according to the invention;

Fig. 4 is an enlarged cross section view of the energy converter and heat exchanger used in the heating system shown in Fig. 3;

Fig. 5 generally illustrates a third embodiment of the system according to the invention.

Throughout all the Figures the same references have been used for indicating equal or functionally equivalent components.

Detailed description of preferred embodiments

With reference to Figures 1, 2a and 2b, there is shown a system for in-line heating of medical fluids according to the invention, the fluid to be infused being disposed in a suitable container 2, such as a bag-like receptacle or a bottle of an intravenous or parenteral fluid such as whole blood and the like that is suspended from a pole 3. At least a flexible tube or supply conduit 4 connects the container 2 to any suitable infusion device, such as a needle 5 or the like for infusing the fluid into a patient at the proper rate. A short length of flexible tube 4a provided with a dripping member 4b is connected to the container 2. Other conventional and known components have not been illustrated for simplicity sake.

The system further comprises an infrared light source 10, located in a housing 11, fed through a cable 13 and connectable through a first optical cable 7 to a second optical cable 8 incorporated in a length of the flexible tube 4, for example located inside the flexible tube, as better shown in Figures 2a and 2b. The optical fiber 8 extends for at least a portion of the flexible tube 4. The optical cable 7 can be connected to the optical cable 8 through an optical coupler 9 of known type as shown in Fig. 2a. The bag 2 is connected to the coupler 9 through the short tube 4a.

In the invention embodiment shown in Fig. 1, each of the optical cables 7 and 8 comprises a single optical

fiber, but it is to be understood that the term "optical cable" generally refers to an assembly of one or more optical fibers adapted to propagate the infrared radiation. More generally, the invention provides for first (7) and second (8) guide means of the infrared radiation, and such means can have any suitable construction, such as for example the structure of a tubular or elongated wave guide with an inner surface reflecting or anyhow propagating a fraction of the infrared radiation.

The infrared source 10 can be any source of infrared radiation emitting the required power, such as a lamp, or a laser device. However any suitable device capable of emitting an infrared radiation with a power comprised between 2 Watts and 400 Watts would be eligible for source 10.

Optical cable 7 is selected so as to transmit most of the infrared radiation being injected from the source 10. On the other hand the second optical cable 8 works like a wave guide allowing a considerable dispersion of the propagating radiation and is further provided with an outer coating 13 of a material that is both opaque to the infrared radiation and has a good heat conductibility. Preferably such coating is realised by applying - over the outer fiber cover - a thin sheet or layer of a plastic material with a proper filler. The disclosed arrangement works as a distributed energy converter that converts the incoming radiant power into heat, and that progressively warms by heat exchange the fluid to be infused and flowing through the flexible tube 4.

According to a further embodiment of the invention (not shown in the drawings), one or more (high dispersion) optical fibers can be embedded into the wall of the flexible tube 4, thus releasing the heat along the whole inner surface of the flexible tube.

In the embodiment of the warming system illustrated in Fig. 3, the flexible tube or supply conduit connecting the container 2 with the infusion device 5 is divided in two portions or sections 31 and 34 connected by an interposed IR-heat converting and heat exchanging device 33 which in turn is connected to the optical cable or fiber 37 from the IR source 10.

As better shown in Fig. 4, the device 33 comprises a tubular or cylindrical housing 40 provided with an inlet 38 and an outlet 39 to be connected to the flexible tube 31 and to the flexible tube 34, respectively.

Inside the cylindrical housing 40 there is disposed a cylindrical member or sleeve 30 closed at one end and forming an inner (cylindrical) chamber 35. Between the cylindrical member 33 and the cylindrical housing 40 there is defined an outer chamber 36 in which flows the physiological liquid, from inlet 38 to outlet 39.

The sleeve 30 is of a material opaque to the infrared radiation and having a good heat conductibility, such as for example aluminum or a properly filled plastic material. The outer surface of the cylindrical member 30 is provided with a helical projecting rib 32, or with fins or other components adapted to disperse the heat and warm the physiological liquid flowing along the outer chamber.

The optical fiber 37, suitably terminated if necessary, is inserted into the inner chamber 35 through a connector 22 in such a way as to disperse the conveyed radiation outside of the fiber so that it impinges the inside of sleeve . Since member 30 is of a material opaque to the infrared radiation, this latter absorbs the IR radiation and is heated by it. Since member 30 is further heat conductive, its temperature is raised and through the projections 32 the liquid flowing in the outer chamber 36 is warmed at the desired temperature.

In the embodiment illustrated in Fig. 5 the IR-heat converting and heat exchanging device 23 is located near the needle 5, in particular the needle 5 is connected by a short length 25 of flexible tube to the device 23. The flexible tube 21 from the container 2 is connected to the device 23 as already illustrated with reference to Fig. 4. This embodiment of the invention is preferred with low flow rates of fluid since this latter is warmed very near to the needle, reducing the heat losses.

Preferably, in the embodiments of Figures 3-5 the container 2, the flexible tubes 4, 31, 34, 21, 25 and the devices 23, 33 are disposable, and in the embodiment of Fig. 1 also the optical fiber(s) 8 is (are) disposable.

Industrial Applicability

The invention applies to the manufacturing of devices or systems for warming a physiologic or medical fluid while the fluid is being infused into a patient.

CLAIMS

1. A system for in-line warming of medical fluids being supplied to a patient comprising,

- a container (2) of said medical fluid to be infused into a patient;

- a flexible supply conduit (4; 31, 34; 21; 25) connected to said container (2) and terminating at one end with an infusion device (5);

- an infrared light source (10) connected at one end of a first guide means (7; 37) adapted to propagate the infrared radiation emitted by said source (10);

- distributed converting means and heat exchanging (8; 38; 33; 23) connected to the other end of said first guide means (7; 37) receiving the IR power from said source (10) and converting it into heat, and progressively transferring said heat to the fluid to be infused flowing along said flexible tube (4; 31, 34; 21) to warm it.

2. A system according to claim 1, characterised in that said first guide means (7; 37) comprise an optical fiber cable comprising at least one optical fiber.

3. A system according to claim 1 or 2, characterised in that said distributed converting means comprises an optical fiber (8) allowing a considerable dispersion of the propagating radiation, and covered by an outer coating (13) of a material that is both opaque to the infrared radiation and has a good heat conductibility, said optical fiber (8) being located inside said flexible supply conduit (4) and extending for a length thereof.

4. A system according to claim 3, characterised in that said optical fiber (8) is connected to said first optical cable (7) through an optical coupler (9).

5. A system according to claim 1 or 2, characterised in that said distributed converting means and distributed heat exchanging means are realised as a device (33; 23) comprising an inner chamber (35) of a material opaque to the infrared radiation, and a surrounding outer chamber (36) in which flows the physiological liquid, and in heat exchange relationship with said inner chamber, said optical fiber (37) terminating in said inner chamber (35) in such a way that this latter is heated by the incoming IR radiation

whereby the liquid flowing in the outer chamber (36) is warmed.

6. A system according to claim 5, characterised in that said inner chamber (35) comprises a cylindrical member (**30**) of a material being opaque to the infrared radiation and having a good heat conductibility, the outer surface of said cylindrical member being provided with projections (32) adapted to disperse the heat and warm the physiological liquid flowing in the outer chamber (36).

7. A system according to claim 6, characterised in that said cylindrical member (**30**) is disposed inside a cylindrical housing (40) provided with an inlet (38) and an outlet (39) to be connected to portions (31, 34) of said flexible tube.

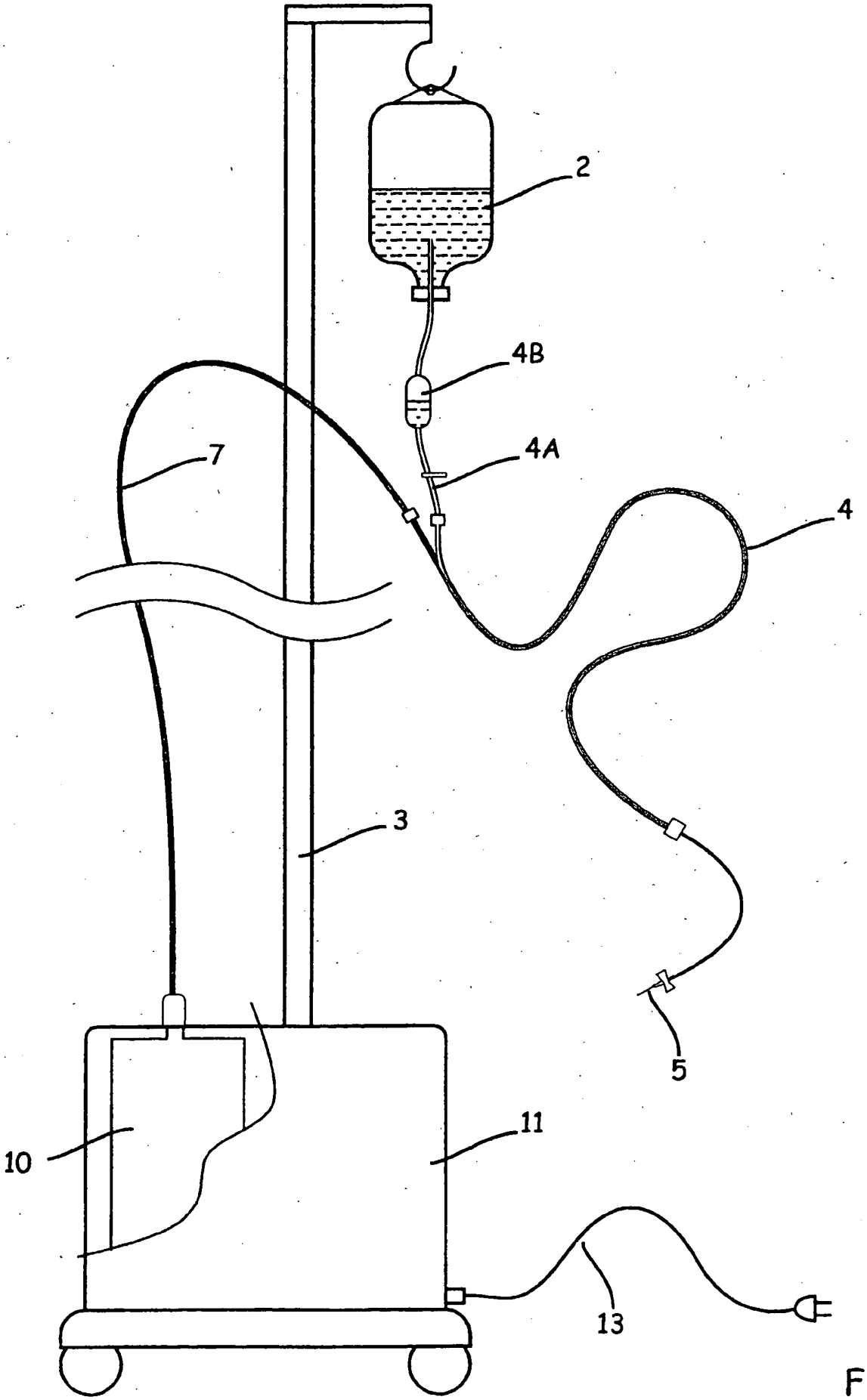

Fig. 1

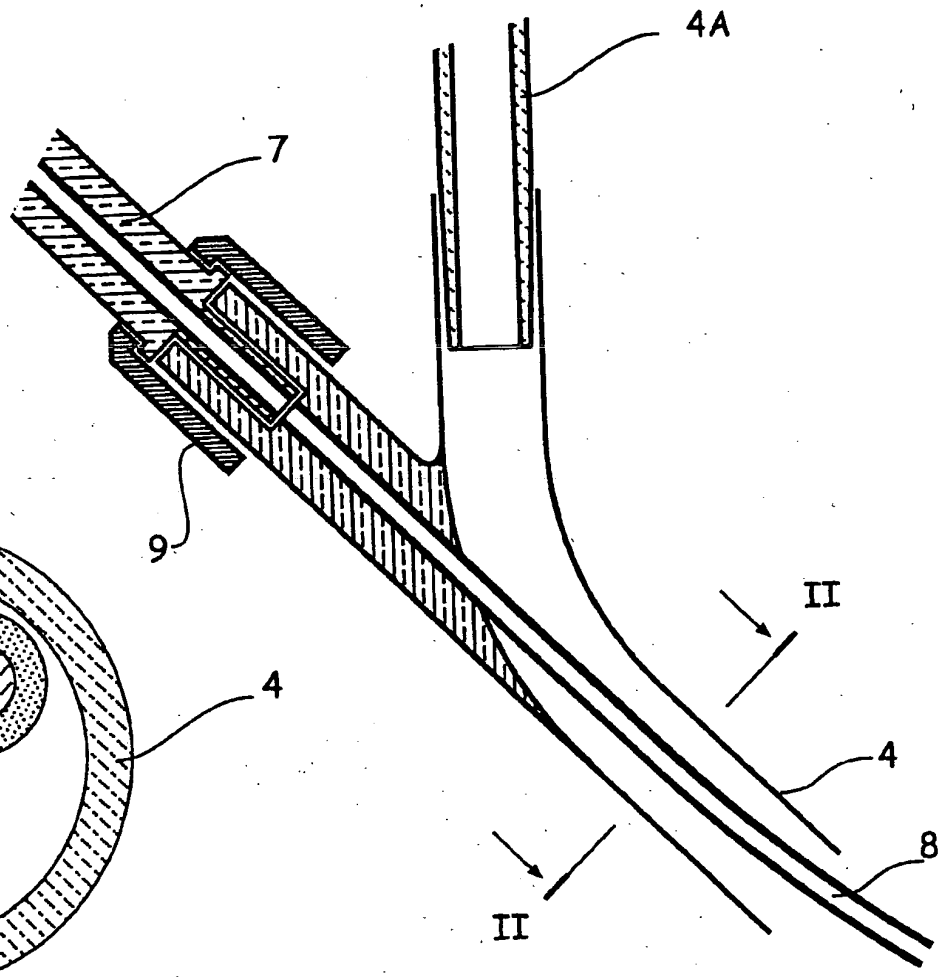

Fig. 2a

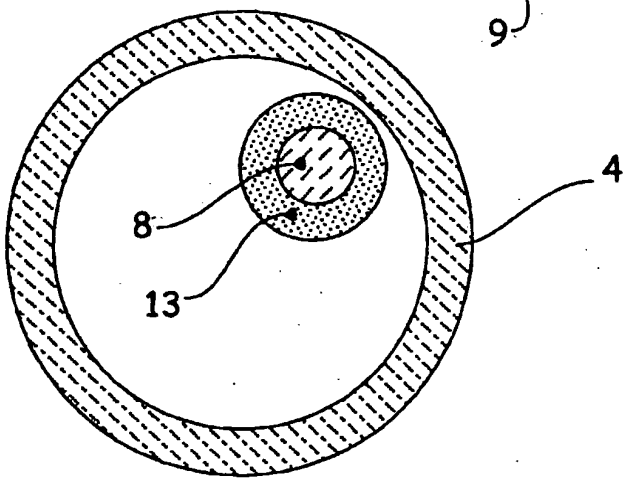

Fig. 2b

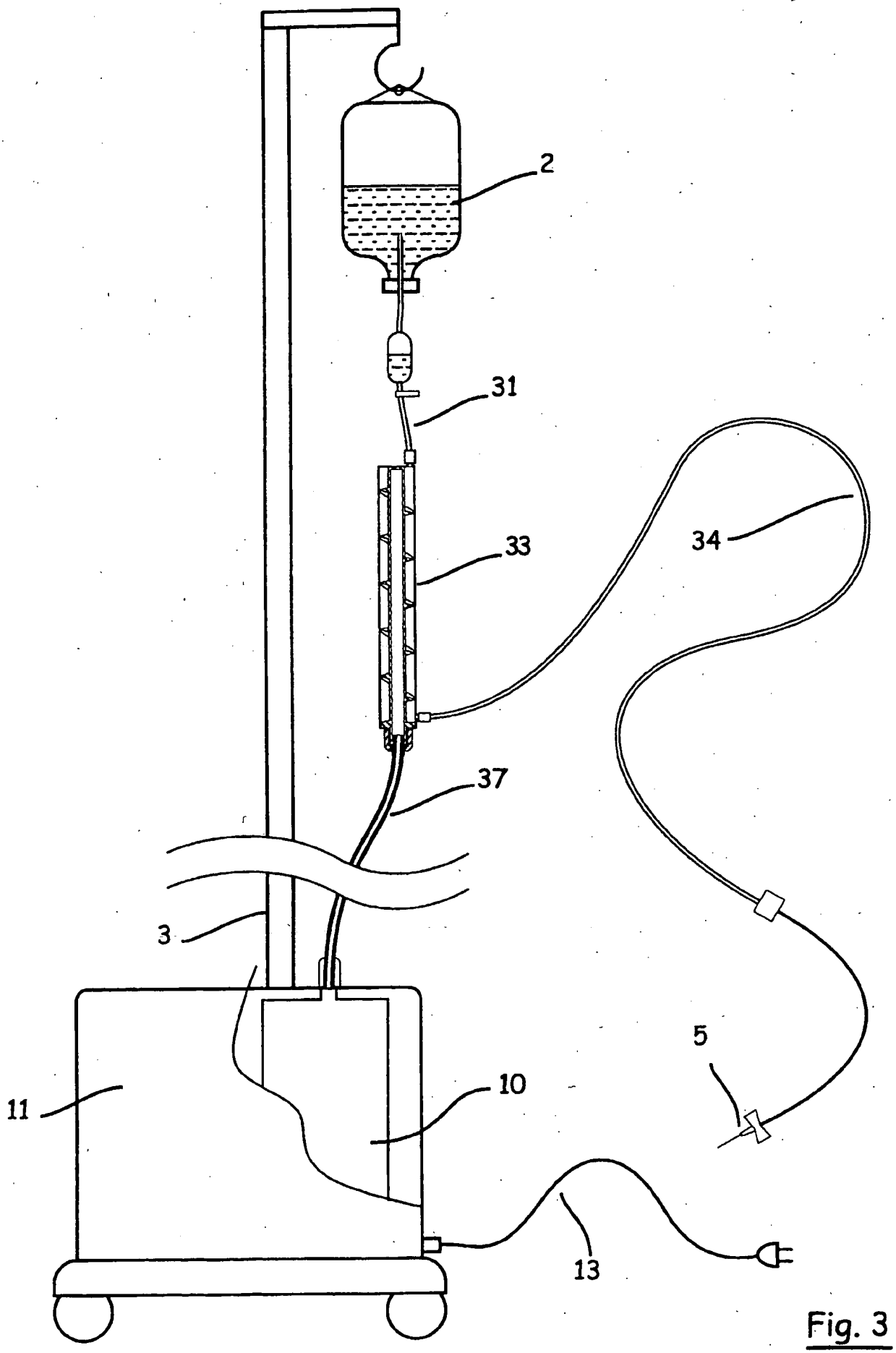

Fig. 3

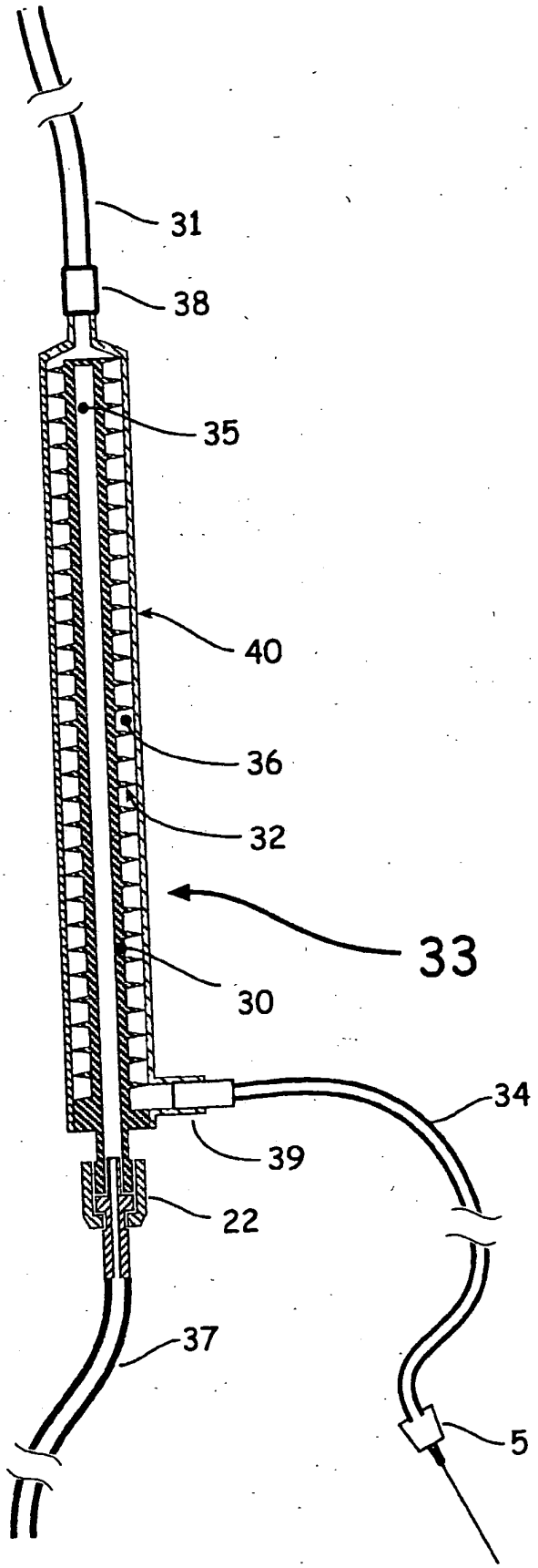

Fig. 4

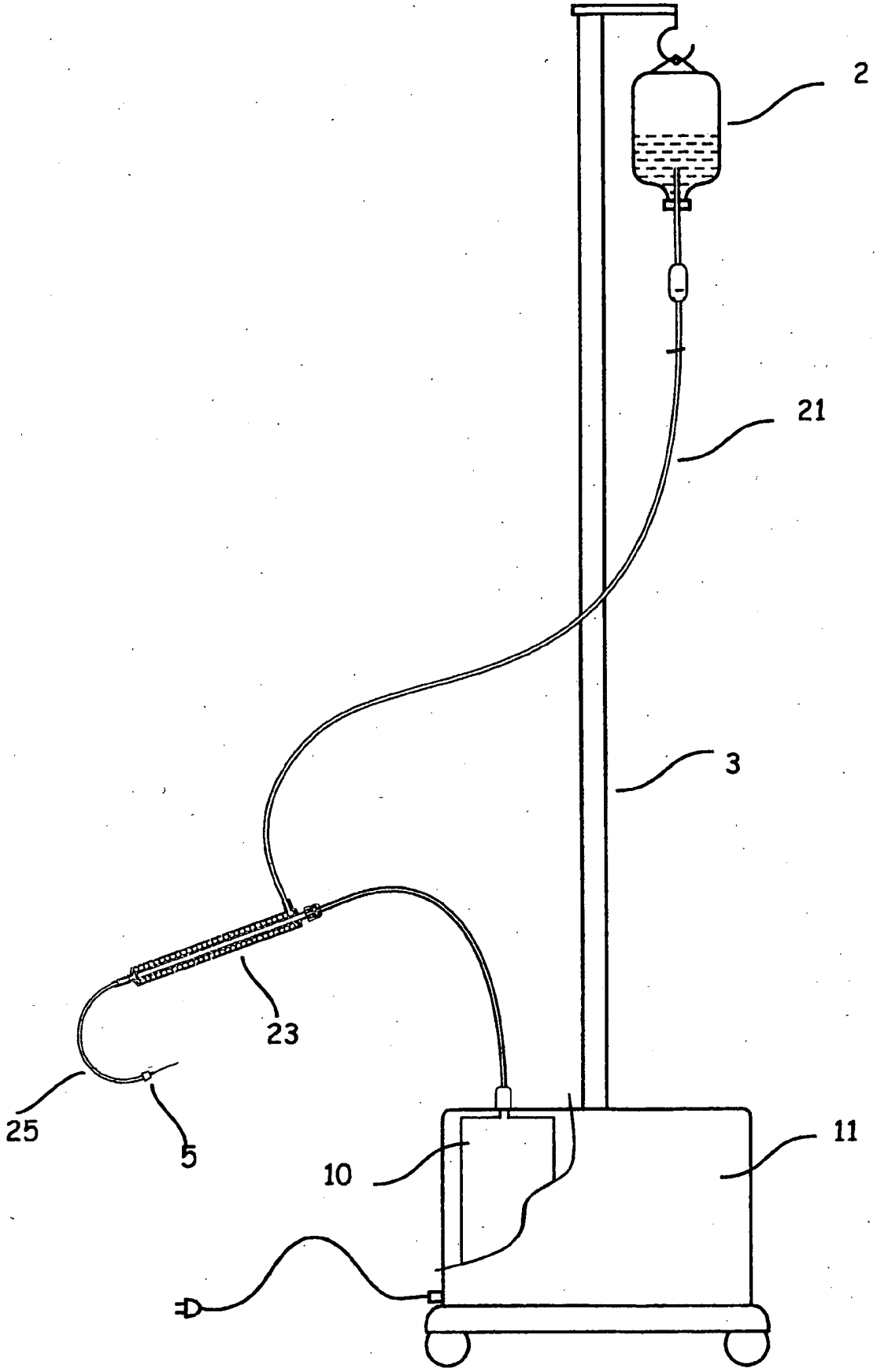

Fig. 5

INTERNATIONAL SEARCH REPORT

Int nal Application No
PCT/EP 00/00804

A. CLASSIFICATION OF SUBJECT MATTER
IPC 7 A61M5/44

According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)
IPC 7 A61M A61F

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic data base consulted during the international search (name of data base and, where practical, search terms used)
EPO-Internal, WPI Data, PAJ

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category *	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
A	GB 2 312 736 A (SPEMBLY MEDICAL LTD) 5 November 1997 (1997-11-05) abstract	1
A	US 3 908 652 A (WEISSINGER HERMANN) 30 September 1975 (1975-09-30) abstract column 4, line 37-48; figures 1,2	1
A	CH 279 543 A (BAUMANN WILLY) 17 March 1952 (1952-03-17) the whole document	1

☐ Further documents are listed in the continuation of box C.

☒ Patent family members are listed in annex.

* Special categories of cited documents :

"A" document defining the general state of the art which is not considered to be of particular relevance

"E" earlier document but published on or after the international filing date

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Date of the actual completion of the international search	Date of mailing of the international search report
21 August 2000	30/08/2000

Name and mailing address of the ISA	Authorized officer
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INTERNATIONAL SEARCH REPORT

Information on patent family members

International Application No
PCT/EP 00/00804

Patent document cited in search report	Publication date	Patent family member(s)	Publication date
GB 2312736 A	05-11-1997	NONE	
US 3908652 A	30-09-1975	NONE	
CH 279543 A		NONE	